IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION, *Plaintiff*, v. CEPHALON, INC., *Defendant*.	**CIVIL ACTION** **No. 2:08-cv-2141**

Plaintiff Federal Trade Commission's Motion to Exclude Opinions of Cephalon's Ten Patent Experts

The Federal Trade Commission respectfully moves this Court for an order excluding the opinions of Cephalon's ten patent experts: (1) Dr. Eugene Cooper; (2) Mr. Bruce Stoner; (3) Dr. Joseph Baranski; (4) Dr. Markus Antonietti; (5) Dr. David Bugay; (6) Dr. Lynn Van Campen; (7) Dr. Robert Williams; (8) Dr. Gerald Dahling; (9) Mr. Paul Gardner; and (10) Mr. Peter Ludwig.

In support of this motion, the FTC (1) submits the accompanying memorandum of law; and (2) joins and incorporates by reference *King Drug* plaintiffs' (a) motion to exclude the opinions of Mr. Stoner and Drs. Cooper and Baranski and (b) motion to exclude Cephalon's expert opinions on infringement.

Dated: April 4, 2014

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FEDERAL TRADE COMMISSION,	)	**CIVIL ACTION**
Plaintiff,	)	**No. 2:08-cv-2141**
v.	)	
CEPHALON, INC.,	)	
Defendant.	)	

Plaintiff Federal Trade Commission's Memorandum of Law in Support of its Motion to Exclude Opinions of Cephalon's Ten Patent Experts (Redacted Version)

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INTRODUCTION

In defense of the hundreds of millions of dollars in reverse payments Cephalon made to its rivals to delay generic Provigil competition for six years, Cephalon has offered in this antitrust case the opinions of ten purported experts on various aspects of Cephalon's '516 particle size patent. This Court has already heard testimony from most of these individuals and has already made various rulings about the '516 patent: that the patent is invalid; that the patent is unenforceable; and that Cephalon's infringement claims relied on an erroneous claim construction and unreliable testing methodology. Notwithstanding these rulings and this Court's March 13 ruling that collateral estoppel bars Cephalon from relitigating patent validity, as well as the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), which made clear that it is "normally not necessary to litigate patent validity to answer the antitrust question," *id.* at 2236, Cephalon recently indicated that it still plans to introduce testimony from these patent experts in the FTC's antitrust case. Regardless of how these opinions are cast, whether as matters of patent strength, reasonableness, or uncertainty, what Cephalon seeks to present is ten expert witnesses to opine about their disagreement with some aspect of this Court's patent rulings. This proposed testimony cannot satisfy the requirements of Federal Rule of Evidence 702.

First, opinion testimony that the '516 patent is valid and enforceable, or that generic modafinil products developed by Teva, Ranbaxy, Mylan, and Barr infringe the patent, cannot help the Court "to understand the evidence or to determine a fact at issue." Fed. R. Evid. 702. The validity and enforceability opinions flatly contradict rulings on these issues that this Court has already made. The infringement opinions are irrelevant first and foremost because an invalid patent cannot be infringed. Moreover, several of Cephalon's experts reject the claim construction

ruling this Court reached in *Apotex.* Finally, the Court has already concluded that the type of particle size testing that forms the basis for the infringement opinions of Cephalon's experts is unreliable, rendering these opinions inadmissible under Rule 702.

Second, even if Cephalon were to try to re-cast its experts' testimony as opinions that Cephalon's patent position was "strong" or "reasonable" at the time of the challenged settlements, the testimony would still suffer from the flaws outlined above that make the opinions inadmissible. Even expressed in these terms, such testimony would necessarily include views on the same factual and legal issues that this Court heard and resolved in *Apotex*. It would therefore not assist the trier of fact—this Court in the FTC's case—in determining any fact at issue. Fed. R. Evid. 702.

Third, and more fundamentally, opinion testimony that Cephalon held "reasonable" or "strong" positions in the underlying patent litigation, or that the outcome of the litigation was "uncertain," likewise fails under Rule 702 because it does not fit any question before this Court under *Actavis*. In *Actavis*, the Supreme Court specifically rejected the view that a reasonable patent position justifies a reverse payment agreement. 133 S. Ct. at 2230-31. Instead, the Court determined that the anticompetitive harm caused by a reverse payment is that it "seeks to prevent the ***risk of competition***." *Id.* at 2236 (emphasis added). The Court emphasized that this harm would flow even from payments associated with a "particularly valuable patent" that faced only a "small risk of invalidity." *Id.* In other words, testimony from Cephalon's ten patent experts that Cephalon had a reasonable or strong patent position would not justify an otherwise large and unexplained payment from Cephalon to its rivals to prevent the risk of competition. Because the existence of a non-sham infringement claim in the patent litigation is not a cognizable justification under *Actavis*, testimony in support of such a defense is inadmissible.

PROCEDURAL BACKGROUND

Cephalon's experts. In the FTC's antitrust case, Cephalon has served or designated reports from ten experts directed to the merits of its RE '516 particle size patent, as set forth below. All of these expert reports were prepared before this Court's validity, enforceability, and infringement rulings in *Apotex*, and before the Supreme Court's decision in *Actavis*. Cephalon did not serve revised or supplemental expert reports from any of these experts during the recent supplemental expert discovery period.

1. *Dr. Eugene Cooper*, a pharmaceutical chemist who offers opinions [redacted]. Dr. Cooper testified as an expert witness at trial in the *Apotex* case.[1]

2. *Mr. Bruce Stoner*, a former official at the U.S. Patent & Trademark Office who offers opinions [redacted]. Mr. Stoner testified as an expert witness at trial in the *Apotex* case.[2]

3. *Dr. Joseph Baranski*, a clinical psychologist who offers opinions [redacted]. Dr. Baranski testified as an expert witness at trial in the *Apotex* case.[3]

4, 5, and 6. *Dr. Markus Antonietti, Dr. David Bugay, and Dr. Lynn Van Campen*, pharmaceutical chemists who offer opinions [redacted]

[1] Dr. Cooper's expert report is attached as Exhibit 1 (hereinafter "Cooper Rep.").

[2] Mr. Stoner's expert report is attached as Exhibit 2 (hereinafter "Stoner Rep.").

[3] Dr. Baranksi's expert report is attached as Exhibit 3 (hereinafter "Baranski Rep.").

[redacted]. Drs. Antonietti, Bugay, and Van Campen testified as expert witnesses at trial in the *Apotex* case.[4]

7. *Dr. Robert Williams*, a professor of pharmaceutics who offers opinions [redacted]. Dr. Williams offered an opinion in the *Apotex* case but did not testify at trial.[5]

8. *Dr. Gerald Dahling*, former in-house intellectual property counsel at several pharmaceutical companies, who offers opinions [redacted]. Dr. Dahling did not offer an opinion in the *Apotex* case.[6]

9. *Mr. Paul Gardner*, a patent lawyer who offers opinions [redacted]. Mr. Gardner was retained by Mylan in the *King Drug*, *Vista Healthplan*, and *Apotex* cases, but Cephalon has notified the FTC that it has designated Mr. Gardner as an expert in the FTC's case.[7]

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[4] Dr. Antonietti's, Dr. Bugay's, and Dr. Van Campen's expert reports are attached as Exhibits 4, 5, and 6, respectively (hereinafter "Antonietti Rep.", Bugay Rep.", and "Van Campen Rep.").

[5] Dr. Williams's expert report is attached as Exhibit 7 (hereinafter "Williams Rep.").

[6] Dr. Dahling's expert report is attached as Exhibit 8 (hereinafter "Dahling Rep."). Dr. Dahling also offers opinions [redacted]. *See* Dahling Rep. ¶¶ 182-226. This motion is not directed at those opinions, but the FTC has filed a separate *Daubert* motion directed at certain of Dr. Dahling's opinions concerning [redacted].

[7] Mr. Gardner's expert report is attached as Exhibit 9 (hereinafter "Gardner Rep.").

10. *Mr. Peter Ludwig*, a patent lawyer who offers opinions [redacted]. Mr. Ludwig was retained by Ranbaxy in the *King Drug*, *Vista Healthplan*, and *Apotex* cases, but Cephalon has notified the FTC that it has designated Mr. Ludwig as an expert in the FTC's case.[8]

Before filing this motion, the FTC asked Cephalon whether, in light of this Court's prior patent and collateral estoppel rulings and the Supreme Court's *Actavis* decision, it would withdraw the opinions of any of the above-listed patent experts, so that motion practice over these experts could be avoided.[9] Cephalon refused to do so without any elaboration as to why these opinions were still relevant and admissible.[10]

This Court's prior rulings. This Court has issued several rulings on the issues addressed by Cephalon's patent experts:

- In October 2010, this Court issued an order construing the claims of the '516 particle size patent. *Apotex, Inc. v. Cephalon, Inc.*, 2010 WL 3933274 (E.D. Pa. Oct. 7, 2010). Among other things, the Court ruled that claims covering specified distributions of modafinil particle sizes do not require that particle size be measured by a single machine, the Hiac/Royko machine, as Cephalon had argued, but rather that particle size may be measured by any "conventional methods known to those of skill in the art." *Id.* at *1, *7-8.
- In November 2011, this Court, following an eight-day bench trial, held that Cephalon's '516 patent is invalid, on four separate grounds, and unenforceable due to inequitable

[8] Mr. Ludwig's expert report is attached as Exhibit 10 (hereinafter "Ludwig Rep.").

[9] *See* Ltr. from Bradley S. Albert to Mark A. Ford (Mar. 21, 2014), attached at Exhibit 11.

[10] *See* E-mail from Mark A. Ford to Bradley S. Albert (Mar. 26, 2014), attached as Exhibit 12.

conduct before the PTO. *Apotex, Inc. v. Cephalon, Inc.*, 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011), *aff'd per curiam*, 500 F. App'x 959 (Fed. Cir. 2013).

- In March 2012, this Court, following a separate three-day bench trial, held that Apotex's generic product does not infringe the '516 patent, finding, among other things, that particle size testing performed by Cephalon's experts was unreliable because it displayed "significant variation" between different tests. *Apotex, Inc. v. Cephalon, Inc.*, 2012 WL 1080148, at *12 (E.D. Pa. Mar. 28, 2012).
- In March 2014, this Court held that collateral estoppel bars Cephalon from relitigating patent invalidity in connection with the materiality element of *Walker Process* fraud claims advanced by plaintiffs in co-pending cases. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2014 WL 982848 (E.D. Pa. Mar. 13, 2014).[11]

The FTC's prior motion. On September 20, 2013, the FTC moved to preclude Cephalon from introducing at trial evidence related to the merits of the '516 particle size patent. The FTC argued alternately that (1) evidence about potential patent validity or infringement is not relevant to the antitrust question presented under *Actavis*; (2) collateral estoppel bars Cephalon from presenting patent-related evidence; and (3) there is no genuine issue of material fact about the invalidity of the '516 patent. This motion is pending.[12] If the Court enters the order the FTC proposed on September 20, 2013, this *Daubert* motion will become moot.

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[11] The Court noted that it would issue a separate opinion addressing the FTC's motion on the preclusive effect of *Apotex* patent rulings. As the Court recognized, the Seventh Amendment issues discussed in its March 13 opinion do not apply to the FTC's case. *Id.* at *5.

[12] On December 20, 2013, the FTC moved for an order that would preclude Cephalon from introducing patent-related evidence from fact witnesses on an independent ground: that Cephalon is using privilege as both a sword (relying on its general counsel's ex-post testimony that the patent was "strong") and a shield (withholding documents and testimony on Cephalon's contemporaneous views on patent strength) (doc. 245). This motion also is pending. If the Court ultimately allows Cephalon fact witnesses to testify regarding patent strength, the FTC may need

ARGUMENT

To be admissible at trial, expert opinion testimony must satisfy three fundamental criteria: (1) the expert must be qualified; (2) the testimony must be reliable; and (3) the testimony must fit the issues in the case. *Schneider ex rel. Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citing Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)). Where, as in the FTC's case, the judge and not a jury is the fact finder, the gatekeeping function under *Daubert* is relaxed—but not eliminated. *See, e.g., Seaboard Lumber Co. v. United States*, 308 F.3d 1283, 1302 (Fed. Cir. 2002). Cephalon bears the burden of establishing the admissibility of its experts' testimony. *Daubert*, 509 U.S. at 593.

I. The opinions of Cephalon's patent experts are unreliable and irrelevant because they contradict prior rulings of this Court

Under *Daubert*'s reliability prong, an expert's conclusions must be based on "good grounds." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 732 (3d Cir. 1994). In addition, an expert's testimony must assist the trier of fact rather than clouding relevant issues. *Id.* at 742-43, 746. Courts have found that one or both of these requirements are not met when an expert's proposed testimony conflicts with prior court opinions on the same subject. *See, e.g., United States v. Cunningham*, 679 F.3d 355, 380 (6th Cir. 2012) (expert's opinion about the nature of a settlement connected to alleged fraud excluded where it "was in direct conflict with the district court's legal conclusion" about the settlement); *In re Elec. Books Antitrust Litig.*, No. 11-MD-2293 (DLC), 2014 WL 1282298, at *14-15 (S.D.N.Y. Mar. 28, 2014) (excluding expert opinion on purported pro-competitive effects of challenged conduct where prior bench trial in government case had demonstrated absence of such effects).

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to introduce limited expert witness testimony to rebut Cephalon's fact witnesses, given that "the primacy of objective evidence over assertions of subjective good faith or lack of knowledge is well established." *Kilopass Tech., Inc. v. Sidense Corp.*, 738 F.3d 1302, 1311 (Fed. Cir. 2013).

A. The validity and enforceability opinions of Cephalon's patent experts contradict this Court's ruling that the '516 particle size patent is invalid and unenforceable

This Court, affirmed by the Federal Circuit, held that Cephalon's '516 particle size patent is invalid under the on-sale bar, for derivation, as obvious, and for lack of adequate written description, as well as unenforceable due to inequitable conduct. *Apotex*, 2011 WL 6090696. Cephalon presents testimony from five patent experts—three of whom testified before this Court in the *Apotex* validity trial—maintaining the opposite. For example:

- In Dr. Cooper's opinion, [redacted][13]
- In Mr. Stoner's opinion, [redacted][14]
- In Dr. Baranski's opinion, [redacted][15]

These conclusions, and the analyses on which they are based, are fundamentally inconsistent with the conclusions reached by this Court in its *Apotex* validity decision. Moreover, Cephalon's experts proffer a number of factual findings that have been specifically rejected by this Court. Because *King Drug* plaintiffs detail rejected factual findings and legal conclusions in their co-pending motion to exclude the opinions of Mr. Stoner and Drs. Cooper and Baranski, we will not repeat them here, but instead join and incorporate by reference *King Drug* plaintiffs' motion.

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[13] Cooper Rep. ¶¶ 7, 24-27, 28-37; *see also* Stoner Rep. ¶¶ 51 ([redacted]), 66-67 ([redacted]).

[14] Stoner Rep. ¶ 25.

[15] *See* Baranski Rep. ¶¶ 9-17.

The validity opinions of Dr. Dahling and Mr. Gardner are similarly unreliable and irrelevant. For example:

- ***Derivation.*** In Mr. Gardner's opinion, [redacted] Gardner Rep. ¶ 30. Dr. Dahling similarly opines that [redacted] Dahling Rep. ¶ 109; *compare Apotex*, 2011 WL 6090696, at *20 ("Lafon did appreciate the significance of smaller particle size;" in any event, "whether Lafon had this appreciation is immaterial.").
- ***On-sale bar.*** In Mr. Gardner's opinion, [redacted] Gardner Rep. ¶ 39; *compare Apotex*, 2011 WL 6090696, at *17 (finding clear and convincing evidence that small-particle modafinil was ready for patenting before October 6, 1993).
- ***Obviousness***. Dr. Dahling highlights [redacted] Dahling Rep. ¶¶ 115-116; *compare Apotex*, 2011 WL

6090696, at *22 (finding one skilled in the art as of 1994 would have measured particle size and then "sought to reduce the median particle size of the modafinil").

Like the opinions of Dr. Cooper, Mr. Stoner, and Dr. Baranski, the validity opinions of Mr. Gardner and Dr. Dahling contradict specific findings and conclusions made by this Court in *Apotex*. The validity opinions of all five of these experts fall squarely within this Court's March 13 collateral estoppel ruling, in which the Court held that Cephalon is bound by and cannot relitigate the *Apotex* invalidity findings. *King Drug*, 2014 WL 982848, at *11-12.[16]

B. The infringement opinions of Cephalon's patent experts contradict this Court's invalidity, claim construction, and non-infringement rulings

Five of Cephalon's patent experts—Dr. Antonietti, Dr. Bugay, Dr. Van Campen, Dr. Williams, and Dr. Dahling—offer opinions regarding infringement by Teva, Ranbaxy, Mylan, and Barr of Cephalon's '516 particle size patent. For example:

- In Dr. Antonietti's opinion, [redacted] Antonietti Rep. ¶ 36; *see id.* ¶¶ 37-53.
- Dr. Bugay served an expert opinion reporting [redacted]. Bugay Rep. ¶ 11.
- In Dr. Williams' opinion, [redacted]

[16] Because a number of the validity opinions expressed by Cephalon's patent experts expressly contradict this Court's invalidity and collateral estoppel rulings, other validity opinions advanced by these experts are irrelevant. For example, various of Cephalon's experts maintain that [redacted] *See, e.g.,* Cooper Rep. ¶¶ 12-21; Stoner Rep. ¶¶ 58-61. These and similar validity opinions are simply not relevant given this Court's holding that the patent is invalid on multiple other grounds.

[redacted] Williams Rep. ¶ 8.

- In Dr. Dahling's opinion, [redacted] Dahling Rep. ¶ 135; *see id.* ¶¶ 139-177.

These opinions are inadmissible as irrelevant to this case. "It is axiomatic that one cannot infringe an invalid patent." *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1368 (Fed. Cir. 2013). It is indisputable that Cephalon's patent is invalid, and that Cephalon may not contend otherwise. Expert testimony regarding whether generic modafinil products infringe an invalid patent is irrelevant and would not assist this Court in resolving any question before it. *See* Fed. R. Evid. 402; Fed. R. Evid. 702.

In addition, the claim construction opinions of Cephalon's patent experts are irrelevant and unreliable because they contradict this Court's claim construction ruling. For example, in *Apotex*, this Court rejected one of Cephalon's preferred claim constructions – that the '516 patent requires use of the Hiac/Royko machine to measure particle size – ruling instead that particle size may be measured by any "conventional methods known to those of skill in the art." *Apotex*, 2010 WL 3933274, at *1, *7-8. The Court's ruling pre-dated the expert reports served in this case, and yet Cephalon's experts rejected it. For example, Dr. Williams stated: [redacted] (emphasis added).[17] Again, Cephalon's refusal to accept this Court's

[17] Williams Rep. ¶ 39 n.4.; *see also* Antonietti Rep. ¶ 30 (same claim construction); Bugay Rep. ¶ 23 n.1 (same). *See also* Antonietti Rep. ¶ 23 [redacted]; Williams Rep. ¶ 39 n.4 (same).

prior rulings violates basic collateral estoppel principles and demonstrates the fundamental unreliability of the expert testimony it hopes to offer.

Finally, the infringement opinions of Cephalon's patent experts are inadmissible as unreliable for the reasons set forth in *King Drug* plaintiffs' co-pending motion to exclude Cephalon's expert opinions on infringement, which the FTC joins and incorporates by reference. Briefly, [redacted].[18] In *Apotex*, this Court found that Dr. Bugay's particle size testing was unreliable because it displayed just such variability. *Apotex*, 2012 WL 1080148, at *12 (finding "Cephalon's testing an unreliable basis for the conclusion that 95% of the modafinil particles in any of Apotex's Canadian tablets are smaller than 220 μm."). Separately, Dr. Williams' opinion that [redacted] is unreliable in light of this Court's holding that Apotex's bioequivalent generic form of Provigil does not infringe the '516 patent.[19]

II. No matter how the testimony is styled, Cephalon's patent experts will address the same factual and legal issues this Court considered and decided in *Apotex*

Though Cephalon's experts have not revised their opinions that the '516 particle size patent is valid and enforceable, Cephalon now appears to have taken a new tack in this case. In recent court filings and appearances, Cephalon has suggested that it will rely on the testimony of its ten patent experts for the propositions that Cephalon had a reasonable-to-strong position in the underlying patent litigation, but that the nature of patent litigation is uncertain and the challenged

[18] *See* Direct Purchaser Class Plaintiffs' Daubert Motion to Exclude Cephalon's Expert Opinions on Infringement, filed Apr. 4, 2014, in *King Drug Co. v. Cephalon*, No. 06-cv-1797 (E.D. Pa.). For example, [redacted].

[19] *See id.*

reverse payment settlements eliminated such uncertainty. For example, in response to a recent question from the Court about its case at trial, Cephalon's counsel responded: "I expect that we will talk about the reasons for settlement and litigation [uncertainty]. . . . We will have expert witnesses who will look at the facts and the patent litigation and give their opinions about the status at the time."[20] Or as Cephalon put it in a November 2013 filing: [redacted][21]

Cephalon's experts cannot establish that Cephalon's patent position was [redacted] without addressing the issues this Court previously resolved in *Apotex*. For example, the generic firms in the underlying patent litigation, like Apotex later, asserted that the '516 particle size patent was invalid under the on-sale bar. Cephalon's patent experts [redacted]. In his opinion, Dr. Dahling opines that [redacted]. Dahling Rep. ¶ 112. But to reach this opinion, Dr. Dahling extensively details [redacted]

[20] Tr. of Proceedings at 70, *FTC v. Cephalon, Inc.* (E.D. Pa. Jan. 23, 2014) (doc. 262) (attached as Exhibit 13); *see also id.* at 166 (statement of counsel for Teva, which owns Cephalon: "[W]e're going to have witnesses, expert witnesses, fact witnesses who are very experienced with handling patent litigation, and I'm saying, you can't know.").

[21] Ceph. Consol. Opp'n to Pls.' Mots. Seeking Summ. J. or Preclusion on [Patent Issues] at 30, *FTC v. Cephalon, Inc.* (filed Nov. 19, 2013) (doc. 235); *see also id.* [redacted]

[redacted].[22] *Id.* ¶¶ 82-96. These are the very issues this Court considered and decided in *Apotex*. And neither the facts nor legal principles relevant to the on-sale bar changed from 2005, when Cephalon was litigating the issue with the generic defendants, to 2011, when this Court reached its *Apotex* validity opinion.

Cephalon's patent experts repeat a similar exercise as to other validity issues, including derivation and obviousness, and unenforceability due to inequitable conduct, all of which were raised by the generic defendants in the underlying patent litigation. Namely, the experts [redacted].[23] And like the on-sale bar, nearly all relevant facts and legal principles pre-date both this Court's *Apotex* opinion and the settlements at issue in this case.[24] No matter the gloss Cephalon puts on them, the experts' conclusions on these facts and legal issues are contrary to this Court's, and therefore irrelevant and unreliable. Nor would they "help the trier of fact"—this Court in the FTC's case—"to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a).

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[22] *See also* Gardner Rep. ¶¶ 31-42 (opining that [redacted]); Cooper Rep. ¶¶ 24-27 ([redacted]); Baranski Rep. ¶ 11 [redacted].

[23] *See, e.g.,* Dahling Rep. ¶¶ 97-112 ([redacted]), 113-118 ([redacted]), 129-134 ([redacted]); Gardner Rep. ¶¶ 22-30 ([redacted]); Cooper Rep. ¶¶ 28-37 ([redacted]), 38-42 ([redacted]).

[24] The only exception is the legal standard for inequitable conduct, as to which this Court applied a higher standard under *Therasense* than the generic firms would have had to meet in the underlying patent litigation. *See Apotex*, 2011 WL 6090696, at *25-28.

Cephalon's infringement experts also opine that [redacted].[25] As explained above, *supra* at 11, these opinions are simply irrelevant. Whether strong or weak, reasonable or unreasonable, Cephalon's infringement contentions would have been of little use with an invalid and unenforceable patent.

III. The opinions of Cephalon's patent experts do not fit any question before this Court under *FTC v. Actavis*

To fit the issues presented in a case and thus be admissible, an "expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Schneider*, 320 F.3d at 404. Where an expert's testimony addresses a question not relevant under the applicable legal standard, it does not meet this "fit" requirement. *See, e.g., Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.") (internal cit. omit.); *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 662-63 (S.D.N.Y. 2007) (proposed expert testimony in trademark dilution case "simply not probative of dilution under the substantive law"); *see also* Fed. R. Evid. 402. Even where an expert's opinion is minimally relevant, it may be excluded if its value would be outweighed by delay or distraction caused by the testimony. *See* Fed. R. Evid. 403; *In re Unisys Sav. Plan Litig.*, 173 F.3d 145, 157-58 (3d Cir. 1999) (affirming exclusion of expert testimony in light of Rule 403); *cf. Paoli*, 35 F.3d at 784 (excluding evidence that would cause "a significant waste of time due to [its] limited relevance, requiring mini-trials" on issues implicated by the evidence).

Testimony from Cephalon's patent experts about the uncertainty of patent litigation or the reasonableness of Cephalon's patent position in the underlying litigation with the generic

[25] *See, e.g.*, Antonietti Rep. ¶¶ 9-10; Bugay Rep. ¶¶ 11-13; Van Campen Rep. ¶ 6; Williams Rep. ¶¶ 9, 33; Dahling Rep. ¶¶ 135-177.

defendants does not fit the issues in this case after the Supreme Court's *Actavis* decision.[26] To be sure, such opinions would have been relevant under the scope-of-the-patent test. Under that test, payments to potential competitors to delay their market entry were immune from antitrust scrutiny so long as the patent holder had a reasonable (non-sham) patent position. *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *abrogated by FTC v. Actavis*, 133 S. Ct. 2223 (2013).[27]

The Supreme Court, however, unequivocally rejected this standard in *Actavis*. The Court recognized that a challenged patent "may or may not be valid, and may or may not be infringed." *Actavis*, 133 S. Ct. at 2231. The problem with a reverse payment, the Supreme Court found, is that it "amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id.* at 2234. Thus, purchasing protection from uncertain competition is the heart of the antitrust concern presented by reverse payments.

Uncertainty may motivate reverse payments, but it does not justify them, according to *Actavis*:

> The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the

[26] *See, e.g.,* Dahling Rep. ¶ 181 [redacted]; Ludwig Rep. ¶¶ 24 [redacted], 79 [redacted].

[27] *See also FTC v. Watson Pharms, Inc.*, 677 F.3d 1298, 1314-15 (11th Cir. 2012) (same standard), *rev'd sub nom FTC v. Actavis*, 133 S. Ct. 2223 (2013); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333, 1335-37 (Fed. Cir. 2008) (same standard), *abrogated by FTC v. Actavis*, 133 S. Ct. 2223 (2013).

> ***risk of competition***. And . . . that consequence constitutes the relevant anticompetitive harm.

Id. at 2236 (emphasis added); *see also id.* (noting "concern that a patentee is using its monopoly profits to avoid the ***risk*** of patent invalidation or a finding of noninfringement") (emphasis added). In other words, even a patent holder's contention that it had a "particularly valuable"—or, in the words of Cephalon's experts, [redacted]—patent position would not justify a reverse payment. Nor would testimony about the uncertainty of the patent litigation aid the fact finder in answering the antitrust question presented under *Actavis.*

For this reason, the Supreme Court repeatedly disclaimed the need for evidence that the underlying patent position of either the brand or generic firm had particular merit. The Court stated that district courts can assess the antitrust implications of reverse payments "without litigating the validity of the patent," *id.* at 2237; that "it is normally not necessary to litigate patent validity to answer the antitrust question," *id.* at 2236; that adoption of a rule-reason-standard "is not to require the courts to insist, contrary to what we have said, that the Commission need litigate the patent's validity," *id.* at 2237; and that "the size of [an] unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself," *id.* at 2236-37. Cephalon's attempt to resurrect the rejected scope-of-the-patent test through the opinions of ten patent experts on the "reasonableness" of Cephalon's patent position has no place at trial.

Instead, as the Supreme Court emphasized, the critical inquiry in a reverse payment case centers on the payment made by the patent holder to its potential challenger. The question is whether "the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.* at

2236. Evidence relevant to this question includes the payment's "size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* at 2237. If a defendant is unable to demonstrate that the payment merely reflects avoided litigations costs and services provided by the generic, then, under *Actavis*, the resulting "unexplained" payment is appropriately understood as a payment to delay generic entry. *See* Aaron Edlin et al., *Activating* Actavis, Antitrust, Fall 2013, at 18 ("Ultimately, then, any explanation must show that there was no payment for delay."). Here, the relevant inquiry focuses on Cephalon's payments to its generic rivals under the cover of licenses to intellectual property owned by the generic firms, supply of active pharmaceutical ingredient, and side product development deals. Cephalon's patent experts have nothing to say about these payments.

Nor did the Supreme Court open the door to a patent-based defense in every reverse payment case when it explained that its prior antitrust decisions involving patent-related restraints considered "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Id.* at 2231. This statement, made when rejecting Cephalon's preferred scope-of-the-patent test, merely reflects that the general rule the Court adopted is "an accommodation of antitrust and patent principles." Edlin et al., *supra*, at 19 & 23 n.45.[28] In any event, if the Court intended that litigation of patent merits would normally be appropriate in reverse payment cases, it would have said so, and not clearly and repeatedly said the opposite.

[28] If not for a patent dispute, the conduct at issue—paying a potential competitor to stay off the market—would plainly be illegal *per se* under the antitrust laws.

CONCLUSION

For the foregoing reasons, the FTC respectfully requests that this Court exclude the testimony of Cephalon's ten patent experts from trial. A proposed order is attached for the Court's convenience.

Respectfully submitted,

Dated: April 4, 2014

/s/ *Markus H. Meier*

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,	**CIVIL ACTION**
Plaintiff,	**No. 2:08-cv-2141**
v.	
CEPHALON, INC.,	
Defendant.	

[PROPOSED] ORDER

AND NOW, this _____ day of _____, 2014, upon consideration of Plaintiff Federal Trade Commission's Motion to Exclude Testimony of Cephalon's Ten Patent Experts, it is ordered that the following experts may not testify at trial: (1) Dr. Eugene Cooper; (2) Mr. Bruce Stoner; (3) Dr. Joseph Baranski; (4) Dr. Markus Antonietti; (5) Dr. David Bugay; (6) Dr. Lynn Van Campen; (7) Dr. Robert Williams; (8) Mr. Paul Gardner; and (9) Mr. Peter Ludwig. It is further ordered that Dr. Gerald Dahling may not testify at trial about U.S. Reissue Patent No. 37,516, patent infringement litigation concerning the RE '516 patent, or the reasonableness of the patent settlement agreements challenged in this case in light of the RE '516 patent.

BY THE COURT:

_____
Mitchell S. Goldberg, J.